REMARKS

This is in response to the Office Action mailed July 28, 2003 in which claims 1-12 and 35-47 were pending. Claims 1-12 and 35-47 were rejected under obviousness-type double patenting, claims 1-10, 35-40 and 42 were rejected over the prior art. Claims 11, 12, 41, 43 and 44 were noted to define patentable subject matter, and claims 45-47 were allowed. With this amendment claims 11, 12, 36 and 39-43 are amended. All claims are in condition for allowance, and reconsideration and notice to that effect is respectfully requested.

Claims 1-12 and 35-47 were rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,296,645. Submitted herewith is a terminal disclaimer to overcome this rejection. The terminal disclaimer overcomes the rejection, which should now be withdrawn.

Claims 1-10, 35-38, 40 and 42 were rejected as anticipated by U.S. Patent No. 5,935,127 to Border. The Office Action stated, "Border discloses an intramedullary nail . . . with a first window defined in its exterior side of the distal end of the nail structure (column 4, lines 23-31)". Column 4, lines 23-31 of the Border patent states, "the above-description is intended for illustrative purposes only, and is not intended to limit the scope of the present invention in any way. For instance, the size and shape of the openings through the metallic portion of the implant can be much larger than the fastener diameters, be located anywhere along the length of the implant, and/or otherwise be varied significantly from the described embodiments without departing from the intended scope of the present invention." Claim 1 is directed to an intramedullary nail structure having a first window defined in an exterior side of the distal end of the nail structure, with the first window having a first window longitudinal length and a first window width not equal to the first window longitudinal length. In the Border patent, the distal end of the nail structure includes two circular or cylindrical holes, that is, the width of both of the distal holes in Border is equal to their longitudinal length. The Border patent states, at column 3, line 36-37, "distal fasteners 35 are positioned, located and drilled in a conventional manner." Border teaches that the **proximal** end of the nail can include a slot so as to receive bone fasteners in either an ante-grade fixation (i.e., through

the trochanter) or reconstruction fixation (i.e,. into the femural head) as selected by the orthopaedic surgeon. Because the proximal end of the nail resides adjacent the trochanter or femural head, Border teaches that the physician can choose an entry location plus or minus an angle theta (in this case 35°) for the proximal placement at column 3, line 24-25. That is, with the shape of the femural head, it is common to permit a significant angular orientation of the bone screws through the proximal end of the nail. Both of these types of attachments of the **proximal** end of intramedullary nails, in the **proximal** end of the femur and corresponding to the shape of the proximal end of the femur, are in the prior art and are also taught in the present application (see page 8, line 14-26).

Border does not disclose or suggest any antegrade or reconstruction fixation into the **distal** end of the nail structure. Because the distal end of the nail does not reside adjacent the trochanter or femural head, there is no disclosure or suggestion to allow the physician to choose an entry location plus or minus an angle theta (in this case 35°) as taught in Border for the proximal placement at column 3, line 24-25. The purpose of the slot in the proximal end of the Border intramedullary nail was to permit such angling of the bone screws. Border does not disclose or suggest that the bone screws at the distal end of the intramedually nail should be disposed at a significant angle relative to the longitudinal axis other than perpendicular to the longitudinal axis of the intramedullary nail. To the contrary, Border expressly teaches the conventional perpendicular attachment of the bone screws at the distal end of the nail. Thus, Border does not disclose or suggest placing the bone fasteners at the distal end of the nail at a non-perpendicular angle to the longitudinal axis. That being the case, Border does not disclose or suggest a distal window having a first window longitudinal length and a first window width not equal to the first window longitudinal length. To the contrary, Border solely discloses the circular or cylindrical openings in the distal end of the nail as taught in the prior art. While Border expressly notes that these circular windows can be larger than the fastener diameters, Border does not disclose or suggest distal openings through the intramedullary nail in any shape other than circular. Accordingly, the rejection of claim 1 is overcome and should be withdrawn. Claims 2-10 depend from claim 1 and are patentable for the same reasons, among others. Claim 35 depends from claim 1 and is patentable as well.

Claims 11 and 12 were objected to as being dependent upon a rejected base claim but were noted to be allowable if rewritten in independent form including all of the limitations to the base claims and any intervening claims. Claim 11 is so amended. Claim 12 is amended into dependent form off of claim 11. Claims 11 and 12 are accordingly patentable as indicated in the Office Action and should now be allowed.

Independent claim 36 was rejected as anticipated by Border, U.S. 5,935,127. The Office Action stated, "regarding claim 35 and 36, Border discloses that the spacer is formed of a non-metal material separately from the nail structure, the first spacer having outer dimensions which correspond to the first window shape, such that the first window shape (sic), such that the first spacer is insertable into the first window and received by the first window to secure the first spacer relative to the nail structure (column 2, lines 45-49)." Column 2, lines 45-49 of Border states, "Except for hollow guide bore 16 that passes completely through nail 10, slot 17 is filled with a solid resorbable material 19 that is secured to metallic portion 12 by any suitable means, such as through the use of molding techniques." However, claim 36 requires the first insert to be "formed of a non-metal material **separately** from the bone support implant" (emphasis added). There is no disclosure or suggestion for the resorbable material 19 of Border to be formed **separately** from the nail structure 10. To the contrary, the resorbable material 19 of Border includes both (a) a cylindrical or tubular cross section (best seen in FIG. 4) which, if formed separately, would be too large for the resorbable material 19 to fit through the screw openings and placed into the cannula; and (b) a portion extending outward into the screw opening, i.e., having the same diameter as the outer diameter of the intramedullary nail wall (best seen in FIG. 3) which, if formed separately, would be too large for the resorbable material 19 to be inserted longitudinally into the cannula. The cylindrical or tubular portion (where lead line 19 is directed) is significantly larger than the width of the window or slot 17. The unmistakable conclusion is that a worker skilled in the art would understand the resorbable material 19 of Border to have been molded in-situ into the nail structure itself (and, most likely subsequently drilled to introduce the cannula). Claim 36 requires the insert to be formed separately from the bone support implant, not with the bone support implant. There is no way that the

resorbable material of Border can be inserted into its position in the nail through the slot 17. Border does not disclose or suggest that the resorbable material can be placed into the slot 17 through a different mechanism. Accordingly, the invention of claim 1 is not disclosed or suggested by Border.

Claim 36 requires the first insert to be formed of a non-metal material separately from the bone support implant. Further, the insert of claim 36 must have "outer dimensions which correspond to the first window shape, such that the first insert is insertable into the first window and received by the first window to secure the first insert relative to the bone support implant". Again, a worker skilled in the art would understand the resorbable material 19 of Border to have been molded in-situ into the nail structure itself in order to have the dimensions shown. The resorbable material 19 of Border does not have outer dimensions permitting it to be "insertable into the first window". As shown in FIG. 4 of Border, the resorbable material 19 of Border is too large in cross-section to permit it to be insertable into the first window. Border, which discloses a shape of a insert which cannot be received into the intramedullary nail if formed separately, does not disclose or suggest the invention defined by claim 36. Claim 35 includes a similar limitation and is patentable for the same reasons, among others. Claims 37 - 40 depend from claim 36 and are patentable for the same reasons, among others.

Further, claim 36 is amended to clarify that the invention defined by claim 36 is not disclosed or suggested by the bone plate disclosure of Border, and further reflecting the purpose of the present invention. As amended, claim 36 requires the first insert to have a bone support implant contacting surface which contacts the bone support implant upon insertion of the first insert into the first window, the bone support implant contacting surface extending generally normal to the longitudinal direction of the bone support implant. After the longitudinal slots 51 are "filled" (again connoting formation in situ, not separate from the bone plate) with resorbable material 52, Border patent at Col. 4, ln. 5-6, the contacting surface is at a significant slope relative to the longitudinal direction in Border. Claim 36, which requires not only a separate formation of the insert but also defines the bone contacting surface extending normal to the longitudinal direction, is neither disclosed nor suggested by Border.

Claim 38 depends from claim 37 and further requires the bone fastener to be insertable through the insert in the same direction as the insert is insertable into the bone support implant. Border, which teaches forming of the resorbable material in-situ in the implant structure, does not disclose or suggest any insertion direction, and thus does not disclose or suggest inserting the insert into the bone support implant in the same direction as the bone fastener is insertable through the insert.

Claim 39 is amended to depend from claim 36. Claim 39 requires the outer dimension of the first insert to be sized to be received in the first window with a press fit. Neither the insert in the intramedually nail of Border nor the insert in the bone plate of Border can be received in the window with a press fit, and Border does not disclose or suggest such a press fit. Claim 39 is accordingly patentable for this reason as well.

Claim 39-44 were rejected as being indefinite, due to typographical errors in the dependency. Claims 39 and 40 are amended to depend from claim 36, providing antecedent basis for "the first insert". Claim 41 was rejected as depending from itself. Claim 41 is amended into independent form, removing this rejection. Claim 42 is amended to depend from claim 41.

Claim 41 was indicated to be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 to include all of the limitations of the base claim and intervening claims. Claim 41 is amended into independent form including the majority of the limitations of claim 36, but not requiring the first insert to be formed separately from the bone support implant. It is believed that claim 41 remains patentable for the reasons originally indicated in the Office Action. Claim 42 is amended to depend from claim 41, and should be allowed with claim 41.

Claim 43 was noted to be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112. Claim 43 is rewritten into independent form including all of the limitations of claim 36. Claim 43 is believed patentable for the reasons originally indicated to contain patentable subject matter. Being now rewritten in independent form, it is believed the claim 43 should now be allowed. Claim 44 depends from claim 43 and should be allowed with claim 43.

Applicant respectfully thanks the Examiner for the allowance of claims 45-47. These claims remain presented in unamended form and remain allowable.

The application containing claims 1-12 and 35-47 is in condition for allowance. Reconsideration and notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at the telephone number listed below if such a call in any way facilitate allowance of the application.

Respectfully submitted,

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